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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,480	03/06/2000	BRIGITTE GICQUEL	0660-0165-0X	5139

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[REDACTED] EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
1645	25

DATE MAILED: 02/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/462,480	GICQUEL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 26July2002.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 56-71 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 71 is/are allowed.

6) Claim(s) 56-70 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. The finality of the previous Office action has been withdrawn.
2. Applicants' Response, received 26July2002, paper#20, is acknowledged. Claims 56 and 57 have been amended. New claim 71 has been added.
3. Claims 56-71 are pending and under consideration.

### **Rejection Withdrawn**

4. The rejection of claims prior 16, 23, 24, 26-29, 31 and 33, now rewritten as new claims 56-70 under 35 U.S.C. §112, second paragraph, indefiniteness for polypeptide expressed by a host "containing" specific polynucleotides, is withdrawn in light of the claim amendments.
5. The rejection of claims prior 31 and 33, now rewritten as new claims 69 and 70 under 35 U.S.C. §112, first paragraph, scope of enablement, for antibody assays or other proteins is withdrawn in light of the claim amendments.

### **Claim Rejections - 35 USC § 112**

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 58 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite that the oligomeric polypeptide comprises 10 “units” of a polypeptide. However, the specification does not define what are the metes and bounds of “unit”.

9. Claims 60-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 60 is drawn to a purified polypeptide comprising at least one antigenic portion of a polypeptide according to claim 57. The open language of claim 57, which is drawn to a polypeptide “comprising” SEQ ID NO:5 or fragments of SEQ ID NO:5, encompasses a polypeptide with additional amino acid sequences outside SEQ ID NO:5. Therefore, the “at least one antigenic portion of a polypeptide according to claim 57” may come from the undefined region which is outside SEQ ID NO:5. Thus, one embodiment of claim 60 is drawn to this undefined region, and therefore, is indefinite. Claims 61-70 do not correct the indefiniteness because there is no requirement that the antigenic portions **only** come from SEQ ID NO:5, but that **an** antigenic portion come from SEQ ID NO:5.

10. Claims 56-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 56 is drawn to a nucleotide sequence which "a biologically active polynucleotide derivative of SEQ ID NO:2" or "a biologically active polynucleotide derivative of SEQ ID NO:2". However, it is unclear what "biologically activity" is being referred to in the claim, and what are the metes and bounds of "derivative".

Embodiment (f) of claim 56 appears to be a purified polypeptide which is encoded by the complement of SEQ ID NO:2, 3, or 4. It is unclear what is the identity/function of such a polypeptide.

Embodiment (g) of claim 56 is drawn to a polypeptide encoded by a nucleotide sequence which hybridizes under stringent conditions with SEQ ID NO:2, 3, or 4. It is unclear what is the identity/function of such a polypeptide.

Claims 57-70 are dependent from claim 56.

### **Conclusion**

11. Claims 56-70 are rejected. Claim 71 is allowable.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

  
RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

January 27, 2003